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Award Number: DAMD17-99-1-9410

TITLE: Body Fat Phenotypes, Sex Hormones and Breast Cancer Risk in Post Menopausal African-American Women

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REPORT DATE: October 2001

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	October 2001	Annual (30 Sep 00 - 29 Sep 01)

4. TITLE AND SUBTITLE
Body Fat Phenotypes, Sex Hormones and Breast Cancer Risk in Postmenopausal African-American Women

5. FUNDING NUMBERS
DAMD17-99-1-9410

6. AUTHOR(S)
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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT ***(Maximum 200 Words)***

African-American (AA) women have the highest breast cancer mortality rate in the U.S. Despite reports suggesting that breast cancer in AA women might be a biologically more aggressive disease, AA women, especially postmenopausal AA women, remain one of the least studied populations in this country, with very little known about their sex hormone profile. Recent findings have suggested that body fat distribution may be a better marker for breast cancer risk than degree of obesity. This is a 5-year cross-sectional study to determine the association between body fat phenotypes and sex hormone profile in postmenopausal AA women. For year two, we were able to continue aggressive recruitment strategies to increase the total number of women interested in participating in the study from 162 for year one to almost triple at 459. This continues to be a very challenging study to undertake, but our study team is undeterred. To date 23 of 43 eligible women have gone through the study protocol. Hormone values for 20 of these women have already been determined. Results from preliminary analyses of hormone and other data on women who have completed the study protocol are presented in this report.

14. SUBJECT TERMS	15. NUMBER OF PAGES
Breast Cancer	21
	16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

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INTRODUCTION:

Breast cancer is a major public health concern for African-American (AA) women in the U.S. AA women experience higher breast cancer mortality rates as well as higher prevalences of obesity and upper body adiposity than Caucasian women. Despite reports suggesting that breast cancer in AA women might be a biologically more aggressive disease, AA women, especially postmenopausal AA women, remain one of the least studied populations in this country, with very little known about their sex hormone profile. Recent findings have suggested that body fat distribution may be a better marker for breast cancer risk than degree of obesity. In this study, we will test the hypotheses that postmenopausal AA women with normal versus upper body fat phenotypes have a sex hormone profile associated with the lowest and highest risk of breast cancer, respectively. This will be a 5-year cross-sectional study comprising 210 healthy postmenopausal AA women (one year postmenopausal up to age 70 years); 70 per body fat phenotype categories of lower ($WHR \leq 0.75$), normal ($0.75 < WHR \leq 0.80$) and upper ($WHR > 0.80$) body fat phenotypes (WHR is the waist to hip circumference ratio). Blood samples will be collected on two consecutive days for determination of estradiol, free estradiol, percent free estradiol, estrone, estrone sulfate, testosterone, free testosterone, percent free testosterone, androstenedione and sex hormone binding globulin, as well as follicular-stimulating hormone and luteinizing hormone. We will determine the subject's body mass index (BMI) and percent body fat using a Hologic Dual Energy X-ray Absorptiometry (DEXA) scanner and collect other relevant data to enable us to control for established and possible confounding factors such as: medical history including family history of breast cancer and a history of benign breast disease; reproductive history such as age at menarche, age at first birth, and number of children; dietary data; physical activity data and others such as use of alcohol, smoking, and exogenous hormones. Multivariate regression models adjusting for various confounders such as age, BMI or percent body fat, age at menarche, parity, and others such as age at first birth as well as various interaction terms between age and BMI, and age and body fat phenotypes, will be conducted to test our hypotheses. This study will add to the virtually non-existent data on sex hormone profile as it relates to postmenopausal breast cancer risk in normal, lower and upper body fat phenotype AA women, independent of body adiposity. It will help us determine whether or not the current thinking of a positive linear association between WHR and breast cancer risk is correct. If our hypotheses are true, future studies would need to control for body fat phenotype; otherwise study findings may provide misleading conclusions. Further, as body fat distribution is potentially modifiable by lifestyle factors such as diet, smoking, drinking alcohol, and physical activity, the possible identification of certain body fat phenotypes as a marker of a hormonal pattern that may increase breast cancer risk in women is of considerable importance.

BODY:

Statement of Work

Body Fat phenotypes, Sex Hormones, and Breast Cancer Risk in Postmenopausal African-American Women

Task 1. Set up study (Months 1 to 4)

- **inform collaborating bodies (such as the GCRC, NEMC[1], and BONREC[2]) of grant award, set up appointments, and finalize arrangements for conduct of the study using their services**— Accomplished according to schedule in year 1.

[1] GCRC, NEMC: General Clinical Research Center, New England Medical Center

[2] BONREC: Boston Obesity and Nutrition Research Center

- **start hiring process for the Project and Enrollment Coordinators with the goal of hiring them by the 3rd month, and training the Project Coordinator by the 4th month**—Accomplished in year 1; Ms. Nikki Leiser is our Research Coordinator for over a year now. The PI did have difficulty retaining an Outreach Coordinator (previously called 'Enrollment Coordinator') because of the low rate of pay as well as the limited percent effort of that position (25% effort or 9 hours a week). Recently the PI was able to secure funding for a similar study on premenopausal AA women. This new grant has a position for an Outreach Coordinator at 25% effort. This allows our current Outreach Coordinator, Ms. Diane Wood, to take on this position at 50% time. To ensure study continuity in the event that our Research Coordinator takes sick leave or vacation time, and to get additional help for our Research Coordinator in case of increased screening of interested women demands, we realize the need to have someone fill in for the Research Coordinator or to assist her in her duties. This is the reason we are currently requesting approval to introduce a new component of this study, the inter-observer-variability component. We have requested and obtained approval from our Tufts HIRC (Human Investigation Review Committee) to undertake an inter-observer variability component of this study to ensure reliable, valid and consistent measurements taken by two or more individuals. However, this change in protocol is still awaiting approval from the DOD HSRRB (Human Subjects Research and Review Board).

- **purchase all supplies needed for year 1 and 2 of study** – Accomplished.

- **finalize, and make copies of all questionnaires, consent forms, and other materials needed for the study**—Accomplished as reported in year 1 progress report.

- **develop flyers, and other materials needed for recruitment of the target population, and get approval of the HIRC for use of these materials** – Accomplished as reported in year 1 progress report.

Task 2. Recruit subjects and collect data (Months 5 to 54)

- **advertise study to the the AA postmenopausal population using various strategies (old and new), and established and new contacts within the AA community** – These activities are in progress. We have had to undertake aggressive labor intensive advertising. The flyers are critical in these efforts. Over the past year, we have distributed our flyers to 250 churches, 25 health centers, 26 private organizations, 52 public organizations, 28 beauty salons, 29 libraries, and other miscellaneous contacts such as malls, stores, and elderly housing complexes. We also hosted a meeting with representatives from 8 community health centers and other community organizations to inform them about this study. Many expressed interest to have the study flyers displayed at their centers, and one (Harvard St. community health center) offered to do a mass-mailing of our study flyers to more than 1,000 of their postmenopausal patients (which we did with poor response). Whittier St. community health center, however, has offered to have our Outreach Coordinator stationed at the center one day a week to inform women about this study. They have also offered use of their examination room for data collection, etc. We are in the process of further negotiations with them about this, and possibly other services that they may be able to provide us such as phlebotomy services. We will continue to work with community health centers to target women and to provide a place in the community that women would feel comfortable going to for study screening purposes and data collection to the extent possible.

  We have narrowed our advertising in the newspapers down to three key newspapers: the Bay State Banner, the Dorchester Community News and South End News based on the number of calls received when the advertisements are in these newspapers, and also for costs reasons. The latter is because the costs of newspaper advertising do add up to exhorbitant amounts and have to be monitored and balanced

out so that enough funds are available for other recruitment strategies as well.

We have participated in more than 25 health fairs and various other community activities (such as the recent "Million Women March Commemoration" and a major mosques- fundraising events). Flyers continue to be distributed in the areas highly populated by Blacks in Boston, namely Roxbury, Dorchester, Hyde Park, and Mattapan.

In addition, we did work with a mass mailing company, ADVO, to mail information about the study to 77,000 households in areas highly populated by our target group, such as Dorchester, Roxbury, and Mattapan, but found that this approach did not give us a good return of interested callers (only about 21 women called in and only 2 of these were eligible).

We continue to receive reserved and slow responses from postmenopausal AA women. Many are suspicious, do not like to be a "guinea pig" (these words are heard quite frequently from this population), and are slow to respond to advertisements. We are on a mission to help dispel these fears from women. We do this by giving presentations within the community, emphasizing the importance of this work for the AA community and answering any questions they may have on any aspect of our study protocol. In general, the responses have been very positive, and many who attended these presentations have volunteered to pass on information about the study to others. We have also been hearing that women prefer to have us screen them in the community. At this time we are in the planning process to make this an option for women. For example, we are working with Ms. Rosette Serwanga, Project Manager of African Health Initiative (AHI) to prescreen women as a group at churches, then have those who are eligible go through the protocol on site at the churches. Transportation will then be provided to take these women to the New England Medical Center (NEMC) for the DEXA scanning which cannot be done offsite. If this strategy works, we will plan to implement it with other community organizations such as the National Council for Negro Women, the Breast Friends program, and community health centers, as well as with other faith-based organizations such as mosques, and other groups. We have also made a new contact with the PI of Reach 2010 Coalition of the Boston Public Health Commission, Ms. Barbara Ferrar, and her Project Manager, Ms. Carol Bray Boy, both of whom are pleased to learn of this work and had asked the PI to give a presentation to their coalition members of about 30 people, which she did. Again the presentation on the importance of this work was well received and many volunteered to help spread word about the study to others.

As mentioned above, we have increased our presentations on the study within the community, and have for the last year given a minimum of 10 presentations at various community organizations and at a library. We will be scheduling to give more presentations to women for year 3 as this has been very well-received by women. For the past year, we were also invited to promote the study on several cable TV shows.

We have not conducted any focus group discussions for this study per se, but had taken advantage of the group presentations mentioned above to get feedback from women on what barriers there are to their participation. Our findings from these discussions include transportation issues (women generally prefer not to have to come to us but prefer that we come to them), emphasis on the need to be sensitive to women's feelings when they called in and are not eligible (there is a need to break this news to them in a way that is sensitive to their feelings – otherwise, they feel rejected, hurt and/or angry), women are extremely busy (many are grandmothers taking care of grandchildren, many are taking care of ailing husbands/other family members, many have multiple demands on their time, etc) and do not find the compensation of $100 provided worth their time. Also many women are dealing with many levels of stress on a regular basis such as deaths in the family (some have multiple deaths in the family in a short space of time, others have family members who had been murdered, etc) such that a study such as this cannot be priority to them. These findings are important in helping us strategize our recruitment efforts.

We will make the necessary efforts to meet the needs of women who are interested but need help to participate (please see our plan to work with the AHI specified above). We will continue to seek other avenues to reach out to women. We are currently researching into the possibility of changing our eligibility criteria to remove the age limit of 70 years and to include smokers, but to control for these variables in our data analyses. This is primarily because only about 9% of women who called in are eligible (42/459).

- **screen interested women for eligibility** -- This is also in progress. Currently, the total number of telephone calls received from interested women are 459 (Appendix 1). Five women did not leave a telephone number to call them. We have already called 454 women with telephone numbers; 424 of these were already screened over the telephone. Thirty women (or 7% of those called) never returned our telephone calls or are "unreachable." The study policy is to try to contact women at least five times before considering them "unreachable." Of those who do not qualify (N=371), reasons for ineligibility include having a disease (N=101; 25 were diabetic and 13 had breast cancer), having first degree relatives with breast cancer (N=26), being premenopausal or perimenopausal (N=76), going into menopause due to surgery (N=63), and having various lifestyle and weight issues that render women ineligible (N=57). Thirty-two women changed their minds about participating. Numbers reported here are not static and changes daily.

- **recruit eligible women into study (expected rate of recruitment is 46 per year for years 1, 2, 3 and 4, and 26 for year 5; total N=210)** -- The number of women eligible after telephone screening is 42 (or 10% of 424 women screened). For year 2, to increase the number of eligible women in this study, two changes in the eligibility criteria were made, and are approved by our Tufts HIRC and the DOD HSRRB. These are changing the eligibility criteria to include (1) women who are at least one year postmenopausal from the originally proposed 4 years postmenopausal, and (2) all eligible women regardless of their level of fat intake from the originally proposed women with at least 30% of calories coming from fat. As stated above, for the third study year, we may change these criteria to include smokers and to remove the 70 years upper age limit. There are currently 11 women out of the 424 screened who are interested but do not currently qualify (i.e., women with "pending eligibility"). These do not currently qualify as they just recently either quit smoking, stopped their weight loss regimen, and stopped taking hormones. We will contact them at a later date to re-screen them.

  To get the eligible women through the study protocol is another challenge (Appendix 2). Of the 42 women who are eligible, 6 changed their minds about participating in the study, 29 have completed going through the consent form process and getting instructions on how to complete the various study questionnaires. This takes place during a "screening appointment." To date we have 7 of the 42 eligibles needing a "screening appointment." Our Research Coordinator continues to call these women on a regular basis asking if they would come in for second level screening. Although they would like to be listed as still interested in participating in the study, these women have not been able to come in for second level screening appointments, or, when the appointments are made, they just did not show up. Of the 29 who have completed second level screening appointments, 1 needs to be scheduled for blood drawing and body measurements appointments, 1 need to return her screening packet, and 23 (compared to 3 last year at this time) have already completed going through the study protocol. Four women who have successfully gone through second level screening changed their minds about participating in the study, and they were quite adamant about the study staff not contacting them any longer. The September 11th World Trade center event also had a great impact on the slow rate of women calling in to participate in the study. One woman lost 7 close friends in that incident. Many who called previously said they needed more time to deal with stress related to the incident.

- Of the 30 new eligible women this year, 7 were from responses to our advertisements in the Bay State Banner, 3 from Dorchester Community Newspaper, 1 from the Metro, 2 from the South End News, 5 from various churches, 1 from a community health center, 4 from mass-mailings, 2 from 'family and friends,' 1 from seminar presentations, 3 from postings, and 1 from an unknown source. Given the challenges with reaching interested women and getting eligible women through the study protocol, our recruitment status is progressing reasonably well. With plans to intensify and better strategize our recruitment efforts for year 3, we expect to increase the momentum such that even more women will be calling per month (our current number of calls for the past 12 months averaged 24, with the a maximum of 53 calls and a minimum of 7 per month). The higher the volume of telephone calls we receive the more likely it is that we will get the number of eligible women going through the study protocol. Comparing these numbers with our premenopausal study numbers, we received a total of 352 calls from interested premenopausal AA within about two and half months of advertising, especially in a free Boston newspaper, the Metro! (Appendix 3) The challenge and labor-intensive nature of conducting a research study in postmenopausal AA are indeed great. This would make findings on this hard to recruit population even more valuable, and much needed. Our study team continues to be committed to face the challenges that this study brings to meet our study goals.

Task 3. Manage incoming data, preliminary analyses, and annual report writing (Months 5 to 54)

- **set up datafiles for medical history, socioeconomic, dietary intake, physical activity, anthropometric**—all of these datafiles have been setup.

- **enter and clean data, and undertake all data quality control measures (ongoing)** – we have entered and cleaned data for 22 of our study participants.

- **conduct preliminary analyses (once a year) for annual report** –we have undertaken preliminary analyses on data for 22 of our study subjects. Serum samples from 20 of these have been determined. The tables of data on basic characteristics of all women, those who are obese, and non-obese, as well as those with lower, normal and upper body fat phenotypes are presented in Tables 1 to 3 (Appendix 4).

  Of the 22 women we have currently recruited for this study, 3 have lower body fat (LBF; $WHR \leq 0.75$), 7 normal body fat (NBF; $0.75 < WHR \leq 0.80$) and 12 have upper body fat (UBF; $WHR > 0.8$) phenotypes. Because of the small number of women we have recruited at this time in general, and specifically within each body fat phenotype, the findings reported here show possible trends as there is not much power for any conclusive findings. Also, for lack of power, we did not run multiple regression analyses on these data to compare levels of hormone between the different body fat phenotypes. Table 1a shows the mean and S.D. of the age, age at menarche, age at menopause, age at first birth, number of children, height, weight, BMI and WHR of all 22 women. Using student's t-tests for unpaired variables, all variables showing the characteristics of women within each body fat phenotype indicated previously, except for WHR (where it is significantly different between NBF and UBF phenotype women), are shown not to be significantly different (Table 1a). The same is true between Non-Obese ($BMI =< 27$; N=11) and Obese ($BMI > 27$; N=9) women (Table 1b), except, as expected, for weight, BMI, and WHR ($p < .001$ for all). Women within the different body fat phenotype categories, as well as within the Non-Obese and Obese categories, were also not found to be significantly different in their intake of the various macronutrients as shown in Tables 2a and 2b.

  Tables 3a and 3b show hormone data for all 20 women, for women within each of the body fat phenotype categories, and for Non-Obese and Obese women. With the few women that we have

currently enrolled in the study, we are unable to show any significant differences in the levels of estrogens, androgens, sex hormone-binding globulin (SHBG), luteinizing hormone (LH) and follicular stimulating hormone (FSH) between women in the LBF and UBF, LBF and NBF, and NBF and UBF phenotypes. However, the same is not true for Non-Obese and Obese women. Even at such low numbers of 11 and 9, respectively, significant differences are observed in certain hormone levels. Obese women had signifcantly higher levels of estrone (E1; p=0.008, by 38%), free estradiol (Free E; p=0.007, by 46%), and lower level of FSH (p=0.047 by 65%) compared to Non-Obese women. In addition, Obese women also showed close to significantly higher levels of estradiol (E2; p=0.06 by 33%), androstenedione (A4; p=0.056, by 34%), and lower levels of SHBG (p=0.069, by 59%). The androgenic/estrogenic hormonal profile found here between Obese and Non-Obese women are indeed similar to those of women at high risk of breast cancer (1-3). Postmenopausal obesity is a known risk factor of breast cancer (4). Our preliminary findings, though non-conclusive due to the small numbers, however, do suggest that postmenopausal AA women who are obese do tend to have a distinct hormonal profile associated with increased risk of breast cancer.

- **prepare report at end of each project year**—Accomplished.

Task 4. Manage blood samples and ship samples for analysis of hormone levels (Months 5 to 54)

- **set up folder for storing blood sample records** –Accomplished.

- **store all blood samples till ready for shipment to Dr. Longcope's laboratory (samples will not be stored longer than 6 months prior to shipment)**—Blood samples for hormone determinations are stored at the GCRC, NEMC, at –70 degrees Centigrade.

- **ship blood samples to Dr. Longcope's laboratory for hormone analyses every 6 months** – Accomplished with serum samples from 20 women.

Task 5. Final analyses and report writing (Months 55 to 60)

- **conduct final data analyses for study** --Will be undertaken at the appropriate time.

- **prepare final report and initial manuscripts** --Will be undertaken at the appropriate time.

KEY RESEARCH ACCOMPLISHMENTS:

None to date.

REPORTABLE OUTCOMES:

Presentations were given to women or representatives of the following: Reach 2010 Coalition members (Boston Public Health Commission), representatives of community health centers and various community organizations at meeting of community health center representatives (at least 100 organizations were invited for this presentation; about 15 representatives from about 10 organizations were present), Harvard St Community Health Center, West Medford Community Center, Women Connecting Affecting Change, Women Services Club, National Council of Negro Women, American Cancer Society (Regional Executive for Prevention and Detection team), Roxbury Multi-Service Center,

Breast Friends Program (Boston Public Health Commission), and Masjid Alhamdulillah. We were also invited guests for the following cable TV shows: "Showcase," Chelsea Community Channel, "Kaleidoscope," and "Making It Real." We have successfully applied for and received funding from the Tufts University College of Citizenship and Public Service (TCCPS) as well as the American Cancer Society to conduct a breast cancer community education program to AA women. We decided to undertake such a program since we find women "thirsty" for information on breast cancer risk factors and healthy lifestyle strategies that have the potential to decrease breast cancer risk, cancer risk in general, and improve overall health, from our presentations within the community. Money from these grants will enable us to provide food and refreshments as well as freebies to women in presentations related to study recruitment activities as well. This way, in addition to providing valuable information to women, we will have a captive audience to promote the study to and to get help with promoting the study from those present.

In addition, we were able to train two high school interns on various aspects of the study this last summer who were in the Health Careers opportunities Program (HCOP). The interns were also able to help promote the study within the community. We have also successfully secured funding for a third year of a similar study on premenopausal AA women. As a result of this grant we are able to hire an Outreach Coordinator who can devote about 20 hours of her time recruiting women, instead of her usual 9 hours per week. This grant also help increased our study advertisement budgets, and promotional strategies since we are now more in touch with younger women whom we are requesting to help spread word about the study to the older women within the AA community.

CONCLUSIONS:

We are encouraged by our very preliminary findings on the differences in hormone levels between Non-Obese and Obese postmenopausal AA women, despite the small numbers. We look forward to getting more data in our third year that would allow us to test our study hypotheses on the sex hormonal profile of postmenopausal AA women with LBF, NBF and UBF phenotypes.

Although the challenges are great and continue to test our study team at all levels, we are determined to get as many women through the study protocol to meet our study goals as possible. As data on this population are limited, it is essential that we continue this work despite all odds. We are strategizing new ways to recruit women for the third year of this project to bring the bulk of the screening and data collection phases to the community with help from community organizations such as the African Health Initiative. We also plan to change the eligibility criteria to include women who smoke and to remove the upper age limit of 70 years completely.

We are encouraged that women welcome presentations on breast cancer risk factors, breast cancer statistics in the AA population, and the importance of our research study. As such we will be making more such presentations within the community to help women understand the work that we do and to dispel any fears and concerns that they may have about research in general, and about going through the study protocol. In addition, being out in the community also help sensitize us further to the needs of the population we are targeting. We continue to persevere with patience and determination to achieve our study goals, learning through our experiences, and incorporating the lessons learned into our future action plans.

Data emanating from this study will add to the virtually non-existent data on the (a) sex hormone profile, and (b) body fat distribution, and body composition of postmenopausal AA women. Significantly more advanced stage and larger tumors, and higher breast cancer mortality rate in AA women compared to Caucasian women have been observed in several studies. In addition to answering questions posed by this main study, the data collected for this study may provide a strong foundation for future work to

determine factors associated with these reported racial differences in breast cancer outcomes. Valuable data on dietary intake and physical activity levels in this population are also being obtained.

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APPENDICES:

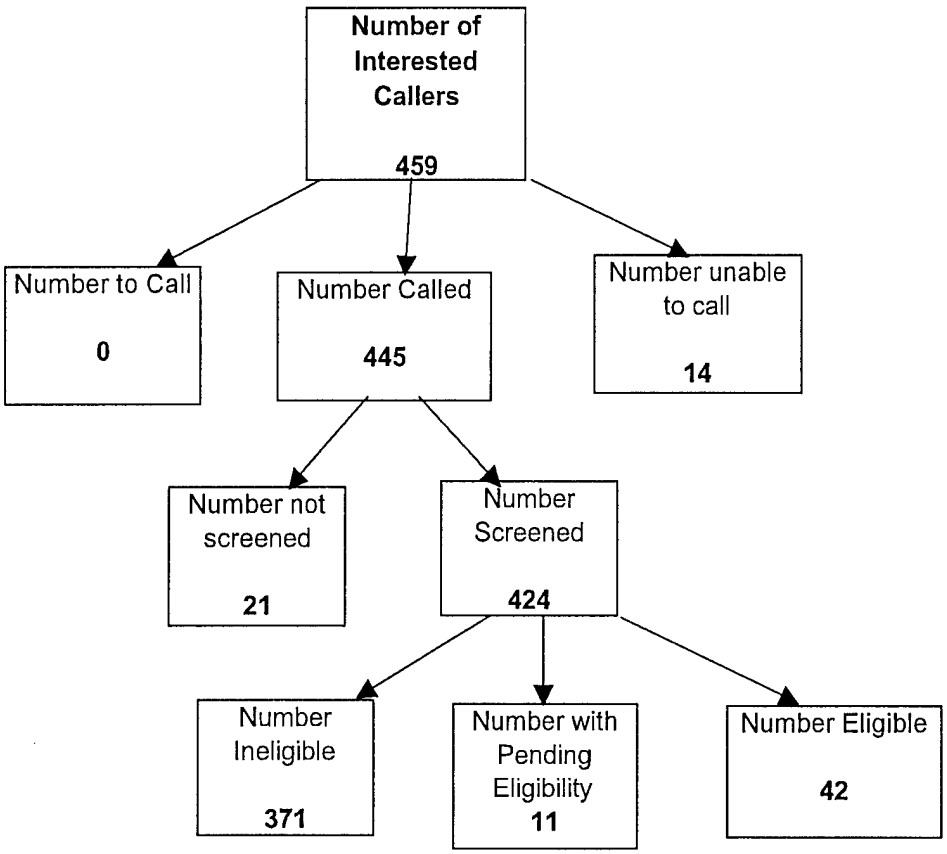
Appendix 1: Study recruitment status

Appendix 2: Status of eligible women after telephone screening

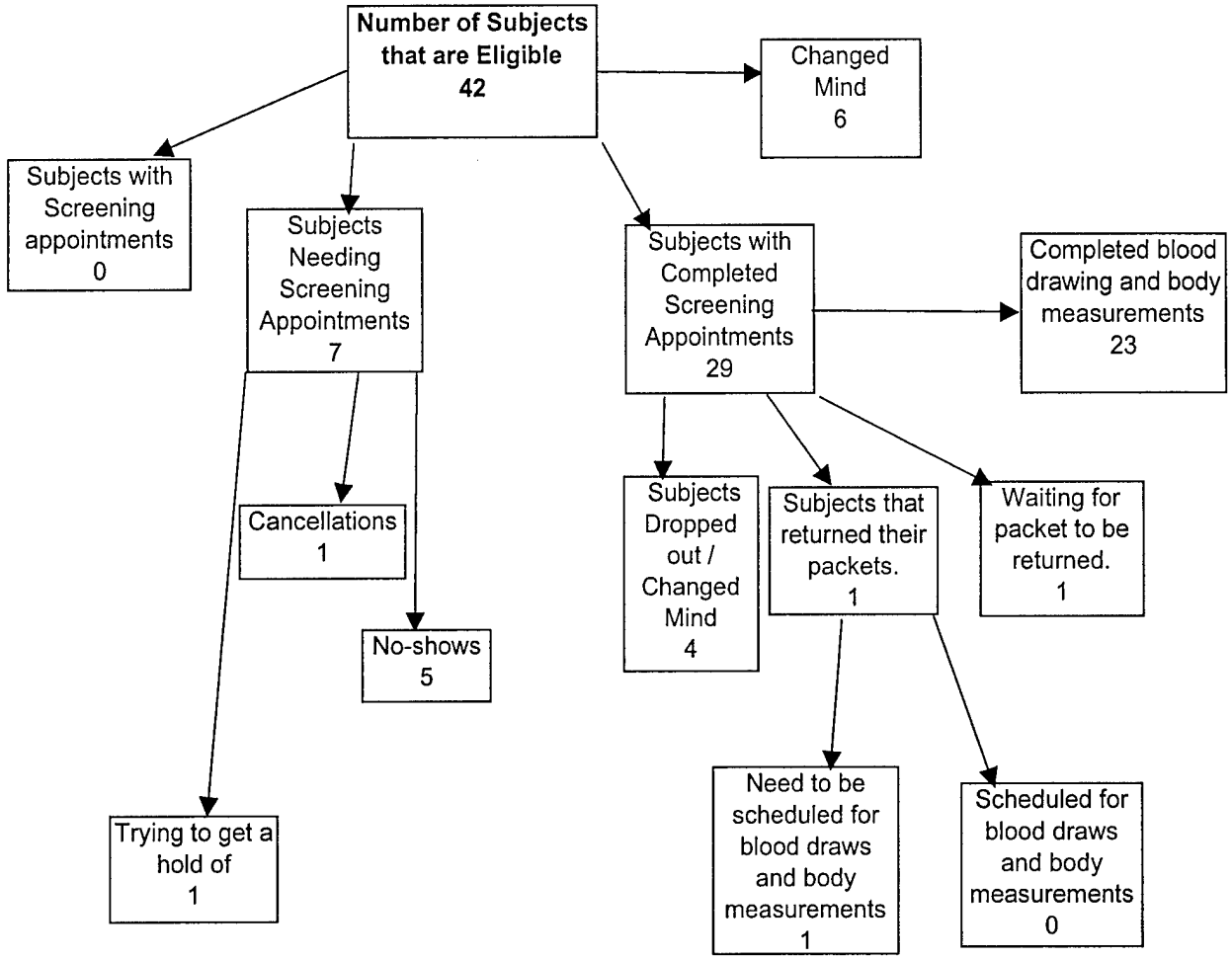
Appendix 3: Recruitment status for premenopausal women study

Appendix 4: Tables 1 to 3

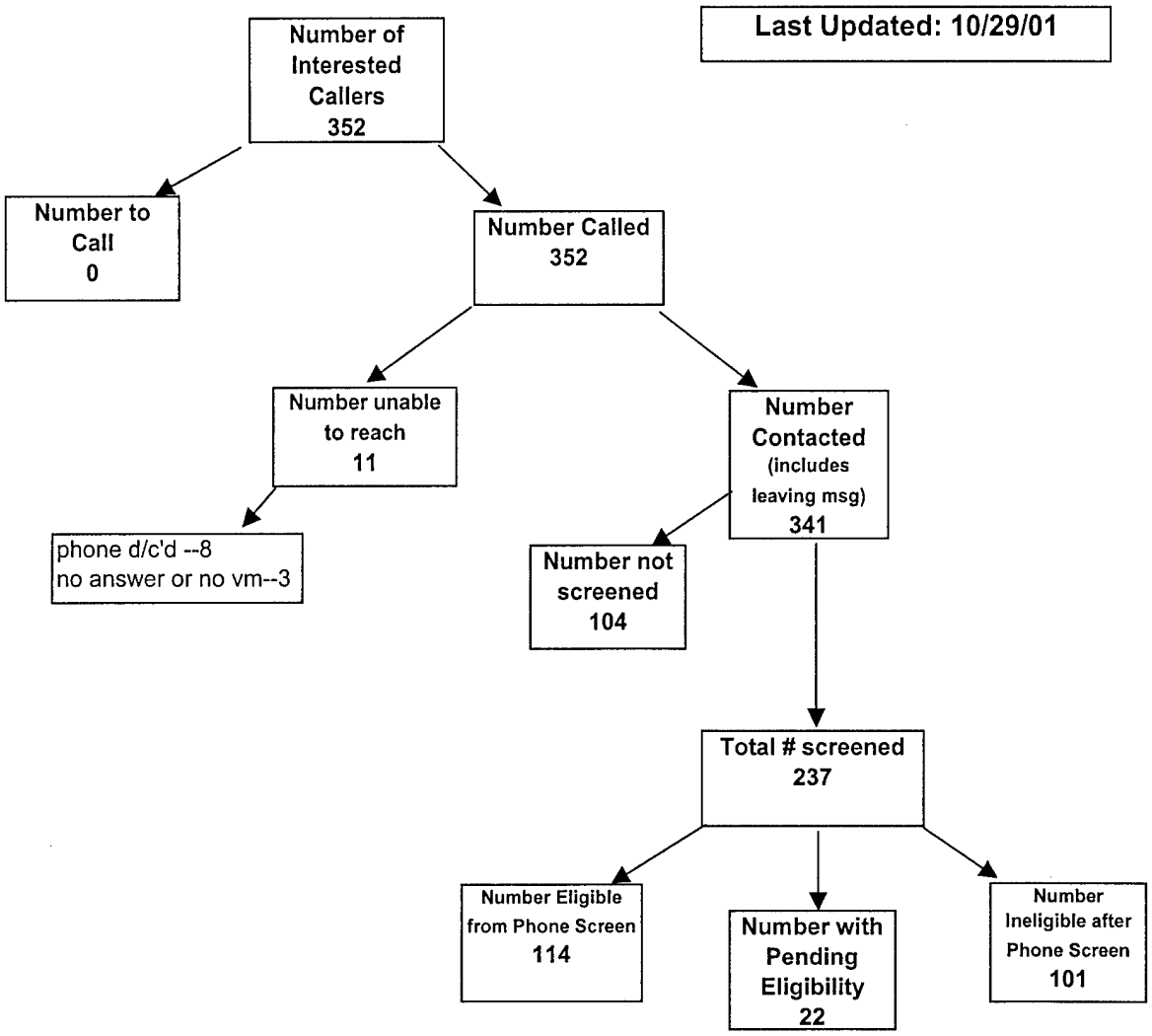
Appendix 1. Study recruitment status



Appendix 2. Status of eligible women after telephopne screening



Appendix 3. Recruitment status for premenopausal AA women study



Appendix 4: Tables 1 to 3

Table 1a. Characteristics of all postmenopausal African-American women, and women with Lower Body Fat (LBF), Normal Body Fat (NBF), and Upper Body Fat (UBF) phenotypes

	All Women N=22		**LBF Phenotype** N=3		**Normal Phenotype** N=7		**UBF Phenotype** N=12		
Variables	***Mean***	***SD***	***Mean***	***SD***	***Mean***	***SD***	***Mean***	***SD***	***P***
Age (y)	56.2	6.7	52.3	4.6	58.4	6.1	55.9	7.3	
Age at Menarche (y)	12.9	1.9	12.3	1.5	13.3	2.1	12.8	1.9	
Age at Menopause (y)	50.0	3.6	47	2.6	51	4.5	50.1	3.1	
Age at First Birth (y) (N=19)	20.1	3.6	22.5[a]	2.1	19.2[b]	2.8	20.1	4.0	
No. of Children	2.6	1.9	1.7	2.1	2.4	2.2	3.0	1.7	
Height (m)	1.60	0.09	1.70	0.11	1.60	0.09	1.70	0.08	
Weight (kg)	74.1	17.0	65.7	8.2	69.8	19.7	79.0	17.0	
Body Mass Index (kg/m)	27.4	4.6	23.8	0.8	26.3	4.3	29.0	4.8	
Waist-to-Hip Ratio	0.80	0.05	0.73	0.01	0.77	0.01	0.83	0.04	<.001*

P values shown for significant variables only (*: between NBF and UBF phenotype women)
P values based on student's t-tests for unpaired variables
[a] : N=2
[b] : N=5

Table 1b. Characteristics of Non-Obese and Obese postmenopausal African-American women

Variables	**Non-Obese N=12** *Mean*	*SD*	**Obese N=10** *Mean*	*SD*	*P*
Age (y)	56.5	8.0	55.9	2.1	
Age at Menarche (y)	12.5	2.1	13.3	1.6	
Age at Menopause (y)	49.2	4.0	50.8	3.2	
Age at First Birth (y) (N=19)	20.7[c]	4.3	19.6[d]	2.8	
No. of Children	2.3	1.9	3.0	1.9	
Height (m)	1.60	0.08	1.70	0.09	
Weight (kg)	62.6	8.9	88.0	13.3	<.001
Body Mass Index (kg/m)	23.8	1.7	31.8	2.6	<.001
Waist-to-Hip Ratio	0.80	0.06	0.81	0.03	<.001

P values shown for significant variables only
P values based on student's t-tests for unpaired variables
[c]: N=9
[d]: N=10

Table 2a. Dietary intake of all postmenopausal African-American women, and women with Lower Body Fat (LBF), Normal Body Fat (NBF), and Upper Body Fat (UBF) phenotypes

	All Women N=22		**LBF Phenotype** N=3		**Normal Phenotype** N=7		**UBF Phenotype** N=12	
Macronutrients per day	***Mean***	***SD***	***Mean***	***SD***	***Mean***	***SD***	***Mean***	***SD***
Energy (Kilocalories)	1903	434	1936	803	2014	426	1830	360
Total fat (g)	72	22	68	39	80	21	68	18
Polyunsaturated fat (g)	16	8	21	21	17	5	14	4
Saturated fat (g)	22	7	20	6	25	8	21	7
Monounsaturated fat (g)	28	9	22	11	31	9	27	9
Cholesterol (mg)	278	129	314	64	331	166	239	110
Protein (g)	75	21	72	32	84	28	71	12
Carbohydrate (g)	250	67	273	95	250	47	243	75
Fiber (g)	19	8	24	12	19	6	18	9
Alcohol (g)	0.53	1.37	0.27	0.27	0.11	0.14	0.84	1.82
Total fat (%)	34	6	30	8	36	4	33	7
Polyunsaturated fat (%)	7	2	8	6	8	2	7	1
Saturated fat (%)	11	3	9	2	11	2	10	3
Monounsaturated fat (%)	13	3	10	3	14	2	13	3
Protein (%)	16.0	3.3	14.8	0.4	16.3	2.4	16.0	4.2
Carbohydrate (%)	53	7	58	7	50	5	53	8

No significant differences found between LBF and NBF phenotype women, LBF and UBF phenotype women, and NBF and UBF phenotype women using students t-test for unpaired variables

Table 2b. Dietary intake of Non-Obese and Obese postmenopausal African-American women

	Non-Obese N=12		Obese N=10	
Macronutrients per day	***Mean***	***SD***	***Mean***	***SD***
Energy (Kilocalories)	1881	468	1930	413
Total fat (g)	70	24	74	20
Polyunsaturated fat (g)	17	10	15	4
Saturated fat (g)	20	7	24	7
Monounsaturated fat (g)	27	10	28	9
Cholestrol (mg)	274	115	284	150
Protein (g)	70	18	81	23
Carbohydrate (g)	255	65	243	73
Fiber (g)	21	10	17	6
Alcohol (g)	0.58	1.48	0.46	1.30
Total fat (%)	33	5	35	7
Polyunsaturated fat (%)	7	3	7	2
Saturated fat (%)	10	2	11	3
Monounsaturated fat (%)	13	3	13	4
Protein (%)	15.2	2.8	16.9	3.8
Carbohydrate (%)	54	6	50	8

No significant differences found between Non-obese and Obese post-menopausal African American women, using student's t test for unpaired variables

Table 3a. Serum hormone levels of all postmenopausal African-American women, and women with Lower Body Fat (LBF), Normal Body Fat (NBF), and Upper Body Fat (UBF) phenotypes

Hormones	**All Women N=20**		**LBF Phenotype N=3**		**Normal Phenotype N=6**		**UBF Phenotype N=11**	
	Geo. mean	***95% CI***	***Geo. mean***	***95% CI***	***Geo. mean***	***95% CI***	***Geo. mean***	***95% CI***
Estrogens:								
Estrone (E1)(pg/ml)	40	(33, 48)	35	(20, 62)	47	(30, 72)	38	(31, 47)
Estrone Sulfate (E1SO4)(pg/ml)	263	(222, 313)	366	(225, 594)	268	(193 ,371)	239	(193, 295)
Estradiol (E2)(pg/ml)	31	(25, 39)	23	(10, 49)	34	(21, 55)	33	(26, 42)
Free Estradiol (Free E2)(pg/ml)	0.61	(0.48, 0.77)	0.37	(0.18, 0.76)	0.60	(0.39, 0.92)	0.70	(0.52, 0.94)
% Free Estradiol (%Free E2)	1.91	(1.72, 2.11)	1.66	(1.36, 2.03)	1.76	(1.46, 2.12)	2.07	(1.81, 2.36)
Androgens:								
Testosterone (T)(ng/ml)	0.16	(0.10, 0.25)	0.12	(0.08, 0.17)	0.12	(0.04, 0.36)	0.21	(0.14, 0.34)
Free Testosterone (Free T)(ng/dl)	1.93	(1.14, 3.26)	1.03	(0.99, 1.07)	1.12	(0.31, 4.03)	3.22	(1.92, 5.40)
% Free Testosterone (% Free T)	1.36	(0.96, 1.92)	0.87	(0.62, 1.22)	0.98	(0.71, 1.34)	1.89	(1.09, 3.31)
Androstenedione (A4)(ng/ml)	0.49	(0.40, 0.61)	0.52	(0.40, 0.69)	0.40	(0.30, 0.54)	0.54	(0.39, 0.76)
Other:								
Sex Hormone-Binding Globulin (SHBG)(nmol/ml)	66	(52, 85)	96	(64, 144)	83	(57, 121)	53	(37, 75)
Luteinizing Hormone (mIU/ml)	26	(22, 30)	28	(27, 30)	29	(20, 43)	23	(19, 29)
Follicular Stimulating Hormone (mIU/ml)	64	(50, 81)	76	(63, 92)	60	(27, 132)	62	(52, 76)

No significant differences found between LBF and NBF phenotype women, LBF and UBF phenotype women, and NBF and UBF phenotype women using student's t-test for unpaired variables

Table 3b. Serum hormone levels of Non-Obese and Obese postmenopausal African-American women

Hormones	**Non-Obese N=11** *Geo. mean*	*95% CI*	**Obese N=9** *Geo. mean*	*95% CI*	*P*
Estrogens:					
Estrone (E1)(pg/ml)	32	(26, 40)	52	(41, 65)	0.008
Estrone Sulfate (E1SO4)(pg/ml)	241	(188, 309)	293	(235, 367)	
Estradiol (E2)(pg/ml)	26	(18, 37)	39	(33, 46)	
Free Estradiol (Free E2)(pg/ml)	0.46	(0.33, 0.65)	0.85	(0.72, 0.99)	0.007
% Free Estradiol (%Free E2)	1.78	(1.59, 1.99)	2.08	(1.75, 2.46)	
Androgens:					
Testosterone (T)(ng/ml)	0.12	(0.06, 0.21)	0.23	(0.13, 0.42)	
Free Testosterone (Free T)(ng/dl)	1.21	(0.63, 2.34)	3.24	(1.57, 6.67)	
% Free Testosterone (% Free T)	1.05	(0.88, 1.25)	1.80	(0.92, 3.53)	
Androstenedione (A4)(ng/ml)	0.41	(0.30, 0.56)	0.62	(0.50, 0.75)	
Other:					
Sex Hormone-Binding Globulin (SHBG)(nmol/ml)	81	(64, 104)	51	(34, 78)	
Luteinizing Hormone (mIU/mol)	27	(23, 32)	24	(18, 33)	
Follicular Stimulating Hormone (mIU/ml)	79	(66, 96)	48	(31, 76)	0.047

Only significant p-values using student's t-test for unpaired variables shown